



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

1981 JUL 20 AM 9:24

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J. Campbell Howard, Jr., M.D.
Medical Director
Schering, Laboratories Medical Research
Schering Corporation
Galloping Hill Road
Kenilworth, NJ 07033

Dear Dr. Howard:

This letter concerns the data on the effectiveness of chlorpheniramine maleate for the treatment of symptoms of the common cold which were submitted by your company on May 5 and April 2, 1980 and by Smith Kline & French Laboratories on May 12, 1978, in relation to the Advisory Review Panel's report and proposed monograph on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products which was published in the FEDERAL REGISTER on September 9, 1976. Based on these data, Smith Kline & French and Schering requested that relief of the symptoms of runny nose, sneezing, itching of the nose or throat, and itchy, watery eyes when associated with the common cold be placed in Category I as labeling claims for OTC antihistamine drug products containing chlorpheniramine maleate.

The Bureau of Drugs has reviewed the data submitted in support of the use of chlorpheniramine maleate in treating the symptoms of the common cold enumerated above. The data submitted included independently conducted, multicentered, double-blind studies in which chlorpheniramine maleate was compared with a placebo in patients with the common cold over a 7-day period. In design and overall methodology, these studies follow the guidelines recommended by the Panel for studying antihistamines in the treatment of symptoms associated with the common cold.

An additional study conducted by a single investigator included 196 patients with the common cold who were followed for a 2-day period. This study was similar to the multicentered studies except for the length of time the patients were studied. The studies provide evidence that chlorpheniramine is significantly more effective than a placebo in alleviating the symptoms of runny nose and sneezing associated with the common cold. However, the

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data do not provide statistical evidence to show that chlorpheniramine is effective in relieving itching of the nose or throat, or itchy, watery eyes associated with the common cold. The Bureau has, therefore, concluded that chlorpheniramine is effective in treating runny nose and sneezing associated with the common cold.

Because the pharmacologic action of the various Category I antihistamines is similar, the Bureau believes that the data submitted for chlorpheniramine allow Category I status for these claims to be extended to all Category I antihistamine active ingredients. The Bureau, therefore, intends to recommend to the Commissioner that the agency place labeling claims for the symptoms of runny nose and sneezing when associated with the common cold in Category I for all Category I antihistamine drugs in the tentative final monograph.

We hope this information will be helpful.

Sincerely yours,

A handwritten signature in black ink, appearing to read "W. E. Gilbertson", written in a cursive style.

William E. Gilbertson, Pharm. D.
Director
Division of OTC Drug Evaluation
Bureau of Drugs